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510(K) SUMMARY

NaviGo™ Workstation

510(k) Number K100784

Applicant's Name:

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and/or

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Date Prepared:

October 11, 2011

Trade Name:

NaviGo™ Workstation

Classification Name:

System, image processing, radiological-Picture archiving and communications system.

Classification:

The FDA has classified Picture archiving and communications system as class II devices (product code LLZ, 21 C.F.R. § 892.2050) and they are reviewed by the Division of Radiology.

Predicate Devices:

3-D Imaging Workstation (Eigen LLC) cleared under K081093

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Indications for Use:

The UC-CARE NaviGo™ Workstation is intended to be used by physicians in the clinic or hospital for 2-D and 3-D visualization of ultrasound images of the prostate gland. Additional software features to assist biopsy procedures include patient data management, multi-planar reconstruction, segmentation, image measurementand 3-D image registration.

The device is specifically indicated to provide information on regional orientation within the prostate to assist biopsy procedures under standard ultrasound guidance, reconstruction of a 3D rendered surface model of the prostate and to display locations for biopsies that have been selected by the physician, as well as storage and future retrieval of this information.

Device Description:

The Navigo™ Workstation is an aiding tool in the management of prostate procedures. The Navigo™ Workstation is designed to assist the physician to transfer and display ultrasound images on the workstation screen, build, display, and manipulate a 3D model of the prostate on screen, provide regional orientation information, archive the images and the 3D model, as well as provide data management solutions. The Navigo™ Workstation enables tracking, displaying and recording of the biopsy needle trajectory location retrieved from the ultrasound probe.

The Navigo™ Workstation is designed to work with standard transrectal Ultrasound system without changing or interfering with the physician's flow of work. The Navigo™ Workstation connects to the Ultrasound system and by tracking the Ultrasound probe's

position, the recorded 2D Ultrasound images are transferred to the Navigo™ Workstation for viewing and 3D modeling.

The 2D images and the 3D model of the prostate are displayed on the Workstation screen, The workstation is equipped with tools to manipulate (rotate, zoom, pan) the model, to add planned biopsy locations on the model and to archive and retrieve the information for further use.

Pathology diagnosis results can be updated on the 3D model and a color display representation gives a visualized status of the prostate.

Substantial Equivalence:

The NaviGo™ Workstation is substantially equivalent to the 3-D Imaging Workstation. The NaviGo™ Workstation has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the NaviGo™ Workstation and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the NaviGo™ Workstation is as safe and effective as the predicate devices. Thus, the NaviGo™ Workstation is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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UC-Care, Ltd.
% Mr. John Smith
Official Correspondent
Hogan & Hartson LLP
Columbia Square, 555 Thirteenth Street, NW
WASHINGTON DC 20004

Re: K100784
Trade/Device Name: NaviGo™ Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 2, 2011
Received: September 2, 2011

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100784

Device Name: NaviGo™ Workstation

Indications for Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use ____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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